510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(21 CFR 807.92)

for the *SecureLoc™ Safety Introducer Needles*

SUBMITTER:

Specialized Health Products®, Inc.
585 West 500 South, Suite 200
Bountiful, Utah 84010

ESTABLISHMENT REGISTRATION NUMBER:

1723684

CONTACT:

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Director, Quality and Regulatory Affairs
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DATE PREPARED:

1/4/2005

NAME OF MEDICAL DEVICE:

Classification Name: Catheter Introducer
Common/Usual Name: General Percutaneous Introducer Needles
Proprietary Name: ***Advanc*Introducer™ and SecureLoc™ Safety Introducer Needles**

DEVICE CLASSIFICATION:

Classification Panel: General Hospital
Class: II
Procode: DYB
Regulation Number: 21 CFR 870.1340

STATEMENT OF SUBSTANTIAL EQUIVALENCE (Predicate Device References):

1. *Safety Introducer Needles (K030135),* B. Braun Medical, Inc., 901 Marcon Boulevard, Allentown, PA 18109.
2. *Majestik™ Angiographic Introducer Needles (pre-amendment),* Merit Medical Systems, Inc., 1600 West Merit Parkway South Jordan, Utah 84095.

DEVICE DESCRIPTION:

The *Advanc*Introducer™ needles consist of a stainless steel needle and a colored translucent standard female Luer lock hub locking connector for rapid (flashback) visualization. The hub has a bevel-up orientation indicator. The hub has been designed to provide the end-user excellent ergonomic tactile balance and stability. The *Advanc*Introducer™ needles are available in one-wall with or without a Seldinger shield. The stainless steel needles are

available with and without an echogenic feature or a specialty coating to enhance percutaneous entry. The needles are available in a range of wall thicknesses, gauges and lengths to match the end-user need.

*Advanc*Introducer™ needles will be marketed to the clinical end-user as sterile, non-pyrogenic, and single use devices. Additionally, the device will be marketed as the safety procedure needle in procedure trays. In the case of being used in procedural kits, the product will be shipped bulk non-sterile to the kitting manufacturer. The *Advanc*Introducer™ will be incorporated into the procedure kit, packaged and sterilized.

SecureLoc™ Safety Introducer Needles have all the same components as the *Advanc*Introducer™ and in addition, incorporates an intuitive easy to use safety guard which is an integral part of the device. SecureLoc™ Safety Introducer Needles are designed for common Introducer needle lengths and gauges. Obturators and stylettes are appropriately available. Stylette handles have an incorporated key to align to the cutting bevel.

The SecureLoc™ Safety Introducer Needle's safety engineered integral safety guard is advanced by the clinician. The safety guard automatically senses the end of the needle and locks a safety guard covering the needle tip. The SecureLoc™ Safety Introducer Needle's easy to use intuitive safety guard reduces the risk of accidental needlestick injuries by shielding the needle tip. A visual, tactile feel, and/or audible confirmation of the locking component over the needle confirms lockout of the safety guard over the needle. The sharps injury prevention guard cannot be deactivated and remains protective through disposal into a sharps container. The safety guard can be activated over stylettes, obturators, and guidewires.

SecureLoc™ Safety Introducer Needles will be marketed to the clinical end-user as sterile, non-pyrogenic, single use devices. Additionally, the device will be marketed as the safety procedure needle in procedure trays. In the case of being used in procedural kits, the product will be shipped bulk non-sterile to the kitting manufacturer. The SecureLoc™ Safety Introducer will be incorporated into the procedure kit, which is then packaged and sterilized.

INTENDED USE:

Both the *Advanc*Introducer™ and the SecureLoc™ Safety Introducer Needles are intended to be used for those patients requiring percutaneous procedures utilizing an introducer needle for guidewire placement for subsequent placement of catheters or other introducer needle required medical procedures.

The SecureLoc™ Safety Introducer Needle's safety engineered integral safety guard is advanced by the clinician. The safety guard automatically senses the end of the needle and locks covering the needle tip. The SecureLoc™ Safety Introducer Needle's easy to use intuitive safety guard reduces the risk of accidental needlestick injuries by shielding the needle point. The safety guard can be activated over stylettes, obturators, and guidewires.

The *Advanc*Introducer™ and SecureLoc™ Safety Introducer Needles will be marketed as both bulk non-sterile single use devices to procedural kit manufacturers and also as sterile, non-pyrogenic, single use devices to clinical end-users. The *Advanc*Introducer™ and SecureLoc™ Safety Introducer Needles may be used in any appropriate patient population.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

It is Specialized Health Products®, Inc.'s conclusion that the ***Advanc*Introducer™** and the **SecureLoc™ Safety Introducer Needles** are substantially equivalent to the following devices: *Safety Introducer Needles (K030135),* B. Braun Medical, Inc., 901 Marcon Boulevard, Allentown, PA 18109 and *Majestik™ Angiographic Introducer Needles (pre-amendment),* Merit Medical Systems, Inc., 1600 West Merit Parkway South Jordan, Utah 84095

A summary of the key technological comparisons follows:

- The *Advanc*Introducer™ and SecureLoc™ Safety Introducer Needles are similar in clinical use, function, materials and use as the predicate Merit Medical Introducer needle devices.
- The SecureLoc™ Safety Introducer Needles have a safety guard that locks a safety guard over the needle tip after the needle is removed from the patient, as does the B. Braun predicate device.
- The SecureLoc™ Safety Introducer Needle's safety guard lock-out can be confirmed by visual means, tactile feel and/or audible means, as does the B. Braun predicate device cited in this submission.

SUMMARY OF PERFORMANCE TESTING:

Comparative testing has been performed on the *Advanc*Introducer™ and the SecureLoc™ Safety Introducer Needles and the predicate devices. Test results indicate that the *Advanc*Introducer™ and SecureLoc™ Safety Introducer Needles perform in a substantially equivalent manner.

SUMMARY OF SIMULATED USE STUDY:

A total of 500 SecureLoc™ Safety Introducer Needles were successfully inserted by clinicians into simulated tissue and activated. No sharps injuries or failures of the integral needlestick prevention guard/safety guard occurred.

CONCLUSION:

The material testing and simulated use data demonstrate that the *Advanc*Introducer™ and the SecureLoc™ Safety Introducer Needle are safe and effective for their intended use, comply with medical device standards, and are substantially equivalent to:

- *Safety Introducer Needles (K030135),* B. Braun Medical, Inc., 901 Marcon Boulevard, Allentown, PA 18109.
- *Majestik™ Angiographic Introducer Needles (pre-amendment),* Merit Medical Systems, Inc., 1600 West Merit Parkway South Jordan, Utah 84095.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Mr. Mark Nelson
Director, Quality and Regulatory Affairs
Specialized Health Products® Incorporated
585 West 500 South #200
Bountiful, Utah 84010

Re: K050023
Trade/Device Name: AdvancIntroducer™ Introducer Needles and SecureLoc™ Safety Introducer Needles
Regulation Number: 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: January 3, 2005
Received: January 6, 2005

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **SecureLoc™ Safety Introducer Needles**

Indications for Use:

- SecureLoc™ Safety Introducer Needles are intended to be used for those patients requiring percutaneous entry procedures utilizing an introducer needle for guidewire placement for subsequent placement of catheters or other introducer needle required medical procedures.
- The SecureLoc™ Safety Introducer Needles are intended to be used as integral safety-needle devices for those patients requiring percutaneous procedures utilizing an introducer needle for guidewire placement for subsequent placement of catheters or other introducer needle required medical procedures.
- The SecureLoc™ Safety Introducer Needle's safety engineered integral safety guard is advanced by the clinician. The safety guard automatically senses the end of the needle and reduces the risk of accidental needlestick injuries by locking a safety guard over the needle tip. The safety guard can be activated over stylettes, obturators, and guidewires.
- Will be marketed as bulk non-sterile single use devices to procedural kit manufacturers and also as sterile, non-pyrogenic, single use devices to clinical end-users.
- May be used in any appropriate patient population.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: ***Advanc*Introducer™ Introducer Needles**

Indications for Use:

- *Advanc*Introducer™ Introducer Needles are intended to be used with those patients requiring percutaneous entry procedures utilizing an introducer needle for guidewire placement for subsequent placement of catheters or other introducer needle required medical procedures.
- Will be marketed as bulk non-sterile single use devices to procedural kit manufacturers and also as sterile, non-pyrogenic, single use devices to clinical end-users.
- May be used in any appropriate patient population.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050023

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)